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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,215	05/02/2001	Annemarie Poustka	012627-019	1167
21839	7590	04/07/2004	EXAMINER	
BURNS DOANE SWECKER & MATHIS L L P			QIAN, CELINE X	
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ALEXANDRIA, VA 22313-1404			PAPER NUMBER	

1636

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

814.

## Office Action Summary

Application No.

09/720,215

Applicant(s)

POUSTKA ET AL.

Examiner

Celine X Qian

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-26 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |  |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

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### DETAILED ACTION

Claims 1-26 are pending in the application.

#### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-15, drawn to an RNA molecule which can bind to a ligand and comprise a sequence region maintaining the three-dimensional structure of the RNA molecule; and a sequence region for the specific binding of the ligand, a DNA sequence codes for said RNA, a vector comprising said DNA and a host cell comprising said vector.

Group II, claim(s) 16 and 17, drawn to an antibody specifically binds to an RNA molecule which can bind to a ligand and comprise a sequence region maintaining the three-dimensional structure of the RNA molecule; and a sequence region for the specific binding of the ligand.

Group III, claim 18, drawn to an antisense RNA which binds to an RNA molecule which can bind to a ligand and comprise a sequence region maintaining the three-dimensional structure of the RNA molecule; and a sequence region for the specific binding of the ligand.

Group IV, claim 19, drawn to a ribozyme that specifically cleaves an RNA molecule which can bind to a ligand and comprise a sequence region maintaining the three-dimensional structure of the RNA molecule; and a sequence region for the specific binding of the ligand.

Group V, claim 20, drawn to a pharmaceutical preparation for preventing or treating diseases which are connected with a disturbed control of gene expression comprising using an RNA molecule which can bind to a ligand and comprise a sequence region maintaining the three-dimensional structure of the RNA molecule; and a sequence region for the specific binding of the ligand.

Group VI, claims 21 and 22, drawn to a method for diagnosis of diseases which are connected with a disturbed control of gene expression comprising using the RNA molecule which can bind to a ligand and comprise a sequence region maintaining the three-dimensional structure of the RNA molecule; and a sequence region for the specific binding of the ligand.

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Group VII, claims 23-26, drawn to a non-human animal comprising a NINTROX gene which is modified by deletion of a homologous sequence and/or insertion of a heterologous sequence, and a method of making said non-human animal.

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-VII do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The “special technical feature” of Group I is an RNA molecule which can bind to a ligand and comprise a sequence region maintaining the three-dimensional structure of the RNA molecule, and a sequence region for the specific binding of the ligand, which is shown by Cech (1995, Biotechnology, Vol.13, page 323) to lack novelty or inventive step over the disclosed ribozyme, and does not make a contribution over the prior art. As such, this technical feature cannot link the invention as a whole to form a single general inventive concept under PCT Rule 13.1.

The invention of the remaining groups each has a unique technical feature not shared by the other groups. The special technical feature of Group II is an antibody that binds to the RNA molecule, which is not shared by the remaining groups. The special technical feature of Group III is an antisense RNA molecule, which is not share by the remaining groups. The special technical feature of Group IV is a ribozyme that cleave specifically of the RNA molecule, which is not shared by the remaining groups. The special technical feature of Group V is a pharmaceutical preparation for treating or preventing diseases, which is not shared by the remaining group. The special technical feature of Group VI is a method for diagnosis of diseases, which is not shared by the remaining groups. The special technical feature of Group VII is a non-human animal comprising a NINTROX gene modification, which is not shared by

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the remaining groups. Therefore, the unity of invention does not exist between the claims of Groups I-VII.

Group I are comprised of multiple inventions which are the products drawn to different and distinct sequences which do not render obvious each other and thus lack unity of the invention. If Groups I is elected, applicants must elect a single invention which is the product drawn to one specific sequence, i.e., the sequence shown in either Figure 1 or Figure 2. Note, this restriction to examination of a single sequence is due to the now very high and undue burden for examining more than one sequence which is caused by the continued exponential increase of size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results. Therefore, the limited resources of the Office no longer permit examination of more than one sequence in an application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine Qian, Ph.D.

A handwritten signature in black ink, appearing to read 'Celine Qian', with a horizontal line extending to the right.